

Dkt. #784-A-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : LIN, et al.

U.S. Serial No.: 10/648,081

Filed : August 25, 2003

For : MODEL EPITHELIAL CELL CULTURES

Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357

December 02, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

COMMUNICATION TO SUBMIT
INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, Applicants would like to direct the Examiner's attention to the following references which are listed below as **Exhibits 1-34** and on Forms PTO/SB/08B (**Exhibit A**). Applicants respectively request that these references be recorded in connection with the above-identified application.

The following references are attached:

1. Beltman, J.McCormick, F., and Cook, S. J. (1996) The selective protein kinase C inhibitor, Ro-31-8220, inhibits mitogen-activated protein kinase phosphatase-1 (MKP-1) expression, induces c-Jun expression, and activates Jun N-terminal kinase. *J Biol Chem* 271 (43): 27018-24 [**Exhibit 1**]

2. Engman, H.A., et al., CYP3A4, CYP3A5, and MDR1 in human small and large intestinal cell lines suitable

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for drug transport studies. J Pharm Sci, 2001.
90(11): p. 1736-51 [Exhibit 2]

3. Frame and Cohen 2001. GSK3 takes centre stage more than 20 years after its discovery. Biochem. J. 359: 1-16 [Exhibit 3]
4. Freund et al. 1998. The cdx-1 and cdx-2 homeobox genes in the intestine. Biochem. Cell Biol. 76: 957-969 [Exhibit 4]
5. He, Y. L., S. Murby, et al. (1998). "Species differences in size discrimination in the paracellular pathway reflected by oral bioavailability of poly(ethylene glycol) and D-peptides." J Pharm Sci 87(5): 626-33 [Exhibit 5]
6. Hilgendorf, C., et al., Caco-2 versus Caco-2/HT29-MTX co-cultured cell lines: permeabilities via diffusion, inside- and outside-directed carrier-mediated transport. J Pharm Sci, 2000. 89(1): p. 63-75 [Exhibit 6]
7. Homma, M., K. Oka, T. Yamada, T. Niitsuma, H. Ihito and N. Takahashi (1992). "A strategy for discovering biologically active compounds with high probability in Chinese herb remedies: An application of Saibokuto in bronchial asthma." Anal. Biochem. 202:179-187 [Exhibit 7]
8. Kawashima, K., K. Saito, A. Yamada, S. Obara, T. Ozaki and Y. Kano (1997). "Pharmacological properties of traditional medicines. XXIII. Searching for active compounds in the blood and bile

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of rats after oral administrations of extracts of Sansohnin." Biol. Pharm. Bull. 20(11): 1171-4
[Exhibit 8]

9. Kim et al. 2002. PTEN and TNF-alpha regulation of the intestinal-specific cdx-2 homeobox gene through a PI3K, PKB/Akt, and NF-kB-dependent pathway. Gastroenterology 123: 1163-1178 [Exhibit 9]
10. Laprise et al. 2002. Phosphatidylinositol 3-kinase controls human intestinal epithelial cell differentiation by promoting adherens junction assembly and p38 MAPK activation. J. Biol. Chem. 277(10): 8226-8234 [Exhibit 10]
11. Lorentz et al 1999. Downregulation of the colon tumour-suppressor homeobox gene Cdx-2 by oncogenic ras. Oncogene 18: 87-92 [Exhibit 11]
12. Madara, J.L. and Trier, J.S. (1987) Functional morphology of the mucosa of the small intestine. In Physiology of the gastrointestinal tract, 2nd edition, ed. Johnson, L.R., Raven Press, New York [Exhibit 12]
13. Mariadason et al. 2000. Divergent phenotypic patterns and commitment to apoptosis of Caco-2 cells during spontaneous and butyrate-induced differentiation. J Cell Physiol. 183: 347-54 [Exhibit 13]
14. Mariadason et al. 2001. Down-regulation of beta-catenin TCF signaling is linked to colonic

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epithelial cell differentiation. Cancer Res. 61:
3465-3471 [Exhibit 14]

15. Moore, J.B. et al., Inhibition of PTH desensitization by inhibition of the G protein-coupled receptor kinase-5 enzyme with Ro 32-0432, FASEB J. Part II 12, A741 (1998) [Exhibit 15]
16. Morgan, J.F., H.J. Morton, and R.C. Parker, Nutrition of animal cells in tissue culture. I. Initial studies on a synthetic medium. Proceedings of the Society for Experimental Biology and Medicine, 1950. 73(1): p. 1-8. [Exhibit 16]
17. O'Loughlin, E.V., et al., Interleukin 2 modulates ion secretion and cell proliferation in cultured human small intestinal enterocytes. Gut, 2001. 49(5): p. 636-43 [Exhibit 17]
18. Owens RB, Smith HS, Nelson-Rees WA, Springer EL. (1976) Epithelial cell cultures from normal and cancerous human tissues. J Natl Cancer Inst 56(4):843-9 [Exhibit 18]
19. Pang, G., et al., Immunologic, functional, and morphological characterization of three new human small intestinal epithelial cell lines. Gastroenterology, 1996. 111(1): p. 8-18 [Exhibit 19]
20. Pontier C, Pachot J, Botham R, Lenfant B, Arnaud P. (2001) HT29-MTX and CaCo-2/TC7 monolayers as predictive models for human intestinal absorption: role of the mucus layer. J Pharm Sci 90(10):1608-19 [Exhibit 20]

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21. Quaroni A, Hochman J. (1996) Development of intestinal cell culture models for drug transport and metabolism studies. *Adv Drug Del Rev* 22:3-52 [Exhibit 21]
22. Rininger J.A. (2001) Utility of a Bioassay-Based Quality Standards Testing Program (BioFit) for Botanical Products in Examining The Science Behind Nutraceuticals. *Proceedings of the AAPS Dietary Supplements Forum.* P83-95 [Exhibit 22]
23. Sears et al. 2000. Multiple Ras-dependent phosphorylation pathways regulate Myc protein stability. *Genes Dev.* 14: 2501-2514 [Exhibit 23]
24. Siavoshian et al 2000. Butyrate and trichostatin A effects on the proliferation/differentiation of human intestinal epithelial cells: induction of cyclin D3 and p21 expression. *Gut* 46(4): p. 507-14) [Exhibit 24]
25. Soubeyran et al 2001. Homeobox gene cdx1 regulates ras, rho, and PI3 kinase pathways leading to transformation and tumorigenesis of intestinal epithelial cells. *Oncogene* 20: 4180-4187 [Exhibit 25]
26. Sun, D., H. Lennernas, et al. (2002). "Comparison of human duodenum and Caco-2 gene expression profiles for 12,000 gene sequences tags and correlation with permeability of 26 drugs." *Pharm Res* 19(10): 1400-16 [Exhibit 26]

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27. Teoh DA, Kamieniecki D, Pang G, Buret AG. (2000) Giardia lamblia rearranges F-actin and alpha-actinin in human colonic and duodenal monolayers and reduces transepithelial electrical resistance. J Parasitol 86 (4) :800-6 [Exhibit 27]
28. Wang, et al. 2001. Inhibition of the phosphatidylinositol 3-kinase pathway contributes to HT29 and Caco-2 intestinal cell differentiation. Gastroenterology 120: 1381-1392 [Exhibit 28]
29. Wang, et al. 2002. Regulation of TRAIL expression by the phosphatidylinositol 3-kinase/Akt/GSK-3 pathway in human colon cancer cells. J. Bio. Chem. 277(39) : 36602-36610 [Exhibit 29]
30. Watson, et al. 2001. Functional modeling of tight junctions in intestinal cell monolayers using polyethylene glycol oligomers. Am J Physiol Cell Physiol. 281: C388-C397 [Exhibit 30]
31. Van de Wetering et al. 2002. The beta-catenin/TCF-4 complex imposes a crypt progenitor phenotype on colorectal cancer cells. Cell 111: 241-250 [Exhibit 31]
32. Wiren, M., K.E. Magnusson, and J. Larsson, The role of glutamine, serum and energy factors in growth of enterocyte-like cell lines. Int J Biochem Cell Biol, 1998. 30(12) : p. 1331-6 [Exhibit 32]
33. Yee, S. (1997). "In vitro permeability across Caco-2 cells (colonic) can predict in vivo (small

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intestinal) absorption in man--fact or myth." Pharm
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34. Yu, AS (2000) Paracellular solute transport: more than just a leak? Curr. Opin. Nephrol. Hypertens. 9(5): 513-515 [Exhibit 34]

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

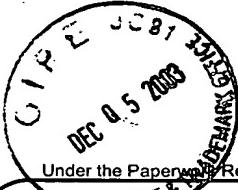
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is given to charge the amount of any such fee to Deposit Account No. 50-1891.

Respectfully submitted,

Albert Wai Kit Chan

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Application Number	10/648,081
Filing Date	August 25, 2003
First Name and Inventor	LIN, et al.
Art Unit	
Examiner Name	

Sheet

1

of

4

Attorney Docket Number

784-A-US

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	Beltman, J.McCormick, F., and Cook, S. J. (1996) The selective protein kinase C inhibitor, Ro-31-8220, inhibits mitogen-activated protein kinase phosphatase-1 (MKP-1) expression, induces c-Jun expression, and activates Jun N-terminal kinase. <i>J Biol Chem</i> 271 (43): 27018-24	
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Sheet 2

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Application Number 10/648,081

Filing Date August 25, 2003

First Name and Inventor LIN, et al.

Art Unit

Examiner Name

OTHER PRIOR ART-NON PATENT LITERATURE DOCUMENTS

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	12	Madara, J.L. and Trier, J.S. (1987) Functional morphology of the mucosa of the small intestine. In Physiology of the gastrointestinal tract, 2nd edition, ed. Johnson, L.R., Raven Press, New York	
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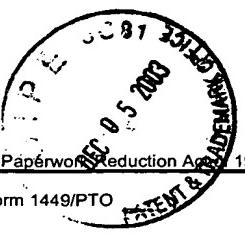
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